

REMARKS

Claims 2-25 and 28-36 are pending following entry of this Amendment. Claims 1, 26, and 27 have been canceled. Each of independent claims 20, 31, and 34 has been amended. Claims 35 and 36 have been added. Claims 20-25 and 28-30 currently stand withdrawn, and newly-added claim 36 should be considered withdrawn so long as claim 20 remains withdrawn. Claims 31 and 34 are the only non-withdrawn independent claims pending after entry of this Amendment.

The amended and newly added claims do not include new matter, as set forth in the following paragraphs.

Each of independent claims 20, 31, and 34 were amended in two ways.

First, each of these claims was amended simply to give a name (“a fluid path”) to the fluid connection within the narrow passageway defined by the separation element. This amendment is non-substantive, in that it simply applies a name to what is already recited in the claim. The name “fluid path” applied to that narrow passageway is also disclosed in the specification, for example at paragraph [0043].

Second, each of these claims was amended to specify that the width of the narrow passageway at the portion of the second step nearest the inlet region in the fluid path (i.e., at the ‘upstream’ edge of the second step) is more than twice the height of the second passageway. This amendment is supported, for example, in paragraph [0035] of the specification, which specifies that fluid flow can continue past particles (“cells” in that paragraph) that cannot fit in the space between the second step and the cover (i.e., the height of the second passageway). Thus, the width of the narrow passageway must be greater than twice the height of the second passageway (since each of the multiple particles has a width greater than the height of the second passageway, but fluid flow can still get past the particles).

Newly added claims 35 and 36 recite a particular embodiment of the apparatus and method that is disclosed in paragraph [0038] of the specification.

The Applicant responds to the Examiner’s rejections in the order in which they occur in the Office Action.

Obviousness-Type Double-Patenting Rejection

In items 4 and 5 of the Office Action, the Examiner rejects all of the pending, non-withdrawn claims as being an obvious variant of the devices in the Hvichia Patent (USPN 6,783,928), with the Sato Patent (USPN 5,023,054) and the Datar Patent (USPN 6,008,040) being cited as obviating references. In the Examiner's view, the Hvichia Patent discloses a device that includes an obstacle interposed between an inlet and an outlet in a body having a void, and each of the Sato and Datar Patents discloses separation of particles using stepped-obstacle devices.

The Applicant respectfully that the Sato and Datar Patents represent art that is not analogous to the field of technology to which the Hvichia Patent corresponds.

The Hvichia Patent is directed to devices in which cells move over/past an obstacle in a closed flow path in which no or substantially no bulk fluid flow occurs (see the Hvichia Patent at col. 4, lines 30-33, for example). In the devices described in the Hvichia patent, cell movement is driven by motive force originating from the cells themselves. The purpose to be achieved using the devices described in the Hvichia patent (assessing movement of cells in the substantial absence of bulk fluid flow) simply cannot be achieved using the bulk-fluid-flow-driven devices described in the Sato and Datar Patents.

By contrast, each of the Sato and Datar patents is directed to devices in which cells move over/past obstacles in a flow path in which bulk fluid flow drives cell movement. (see, e.g., Sato at col. 5, lines 45-48, and Datar at col. 4, lines 42-45). The purpose to be achieved using the devices described in the Sato and Datar Patents (forcing cells past fixed obstacles by way of bulk fluid flow) simply cannot be achieved using the cell-motility-driven devices described in the Hvichia patent. For that reason, no skilled artisan would consider combining the teachings of the Hvichia Patent with the teachings of either of the Sato and Datar Patents.

For the foregoing reasons, the Applicant respectfully contends that the Examiner may not properly combine the teachings of the Hvichia Patent with those of the Sato and Datar Patents to support the obviousness-type double-patenting rejection of the claims. Reconsideration and withdrawal of that rejection are respectfully requested.

Anticipation Over Sato

In items 6 and 7 of the Office Action, the Examiner rejects claims 2, 4-12, 14, 31, 32, and 34 pursuant to 35 U.S.C. § 102(b) over the Sato Patent. In the Examiner's view, the Sato Patent discloses devices that embody the apparatus recited in the rejected claims.

The Applicant respectfully contends that Sato fails to disclose the device that is claimed by the Applicant and, indeed, that a device constructed according to the disclosure in Sato cannot perform the functions performed by the Applicant's claimed apparatus. The Applicant has amended each of independent claims 20, 31, and 34 to highlight the difference between Sato's device and the apparatus recited in the Applicant's claims.

Simply put, the Sato device is a device for passing cells through a narrow channel in a one-cell-at-a-time fashion – with each channel therefore being susceptible to clogging by a single impassable cell. By contrast, the Applicant's claimed apparatus has steps wide enough to accommodate multiple impassable cells without clogging. As stated in the Applicant's specification (page 9, lines 23-25), *"if one portion of a step becomes clogged with cells that cannot fit in the space between the step and the cover or body, fluid flow can continue along the remaining width of the step."* In fact, the Applicant's claimed apparatus is intended to operate by accumulating impassable particles/cells on one or more steps thereof. Thus, the Applicant's claimed apparatus differs substantially from the Sato device in that its narrow passages do not become easily clogged by single impassible cells, while Sato's device requires this.

Sato discloses a blood filtering device (col. 3, lines 7-10) that includes a bank **14** that has multiple microscopic grooves **15** extending across it (see Figs. 2A and 2B). The Sato device can be used to assess the volume, size, and deformability of blood cells (col. 1, lines 51-57) passing through the grooves. Significantly, the grooves **15** of Sato's device must have a width that is on the order of (i.e., slightly narrower than or not significantly wider than) the diameter of blood cells – otherwise the device is inoperable.¹ The grooves **15** of the Sato device cannot accommodate passage of multiple cells in parallel.

¹ Sato at col. 8, lines 3-10, recognizes that clogging of too-small grooves renders the device "unusable." Sato discloses at col. 6, lines 41-55, that a device having grooves significantly larger than the diameter of blood cells can be used, but only for measurement of viscosity – a bulk fluid property unrelated to filtration or segregation of cells/particles in the fluid, and thus irrelevant to the Applicant's claimed devices.

By contrast, in the apparatus claimed by the Applicant, the width of the narrow passageway must be sufficient to accommodate passage of multiple particles (e.g., cells) in parallel. As recited in claim 31, as amended herein,² the width of the narrow passageway through which particles (e.g., cells as in Sato) pass at the “upstream” edge (i.e., the edge nearest the fluid inlet region in the fluid path) of the second step is more than twice the height of the narrow passageway above the second step (i.e., more than twice the width of particles capable of passing through the “second passageway” recited in the claim).

Because Sato does not disclose any apparatus having narrow passages capable of accommodating passage of multiple particles immediately upstream of the second (i.e., narrower) step, Sato does not anticipate any of the Applicant’s claims. Stated another way, Sato fails to disclose a multi-step particle-separating apparatus in which the width of the narrow passageway at the portion of the second step nearest the inlet region in the fluid path is more than twice the height of the second passageway.

The Examiner makes reference to Figure 8 of Sato, which arguably illustrates a two-“step” construction, with one of the purported “steps” being a groove **27** and the other purported step being a guide portion **28**.³ However, close examination of Sato (see col. 7, lines 32-66) reveals that both grooves **27** and guide portions **28** of Sato accommodate only a single cell at a time. That is, the purpose of guide portions **28** is to ‘corral’ a single cell by enclosing and orienting it within the space bounded by the guide portion **28**, thereby causing the cell to enter groove **27** in a more uniform manner, relative to a groove **27** not having an associated guide portion **28**. If guide portion **28** were able to accommodate more than one cell at a time, then it would be incapable of performing the cell-enclosing and -orienting function for which it is intended by Sato. Thus, it is clear that each item (i.e., items **27** and **28**) within this purported two-“step” structure of the Sato device is capable of accommodating only a single cell at a time. This is contrary to what is recited in the Applicant’s amended claims (i.e., that, at the portion of

² Claim 34 has been similarly amended. Presently-withdrawn claim 20 has been similarly amended in order to facilitate its rejoinder and allowance.

³ Item **27** is identified as a “filter section” in Sato without further explanation. It appears clear from the context that item **27** in Sato has substantially the same structure and function as the “groove” **15** disclosed in Sato. Items **28** and **28a** are referred to alternatively in Sato as “guide portions” and “grooves.” For the sake of clarity in this Amendment, the Applicant refers to items **27** and **28** of Sato as “grooves” and “guide portions,” respectively.

the second step nearest the inlet region in the fluid path, the width of the narrow passageway is more than twice the height of the second passageway and can thus accommodate two or more cells/particles without obstructing fluid flow). Sato therefore does not anticipate the Applicant's amended claims.

For the foregoing reasons, the Applicant respectfully contends that Sato fails to anticipate any of claims 2, 4-12, 14, 31, 32, and 34. Reconsideration and withdrawal of the Examiner's rejection of these claims pursuant to 35 U.S.C. § 102(b) over Sato are respectfully requested.

Obviousness Over Sato Alone

In item 8 of the Office Action, the Examiner rejects claims 3, 8-13, and 19 pursuant to 35 U.S.C. § 103(a) over the Sato Patent. The Examiner's overall view of the Sato Patent was described above in connection with the anticipation rejection. In the Examiner's view, the recitations in the Applicant's claims 3, 8-13, and 19 are obvious design choices or obvious variants of Sato's device.

The Applicant respectfully demurs.

Even if it were true that the Applicant's recitations represent merely obvious design choices or variants, Sato nonetheless fails to disclose either the apparatus recited in the Applicant's independent claims 20, 31, and 34 or an obvious variant thereof. That is, Sato does not disclose an apparatus capable of accommodating multiple cells/particles at the 'upstream' portion of the second step recited in the Applicant's claims, nor does Sato disclose information that suggests that such an apparatus should, or even could, be made by altering the Sato device in ways claimed by the Applicant. Thus, Sato fails to render obvious any of claims 3, 8-13, and 19, for substantially the same reasons (stated above) that Sato fails to anticipate any of the Applicant's claims.

Simply put, operation of the Sato device depends on one-at-a-time passage of cells through the narrow passages thereof. By contrast, the Applicant's claimed apparatus must accommodate multiple cells in parallel without occluding fluid flow. There is no teaching or suggestion in Sato that would lead a skilled artisan to abandon the one-at-a-time cell passage

aspect of the Sato device and to instead fashion an apparatus capable of accommodating multiple cells in parallel.

The Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 3, 8-13, and 19 pursuant to 35 U.S.C. § 103(a) over the Sato Patent.

Obviousness Over Sato in View of Hale

In item 11 of the Office Action, the Examiner rejects claims 15-17 as being obvious pursuant to 35 U.S.C. § 103(a) over Sato in view of the Hale Patent (U.S. Patent No. 5,089,384). In the Examiner's view, the Sato Patent renders the apparatus recited in claims 15-17 obvious, but for recitation in these claims of a device for manipulating or killing cells. The Examiner asserts that Hale discloses such devices.

The Applicant respectfully demurs.

Even if Hale discloses devices for manipulating or killing cells that satisfy the recitations of claims 15-17, Sato fails to obviate the remainder of the apparatus claimed by the Applicant, for substantially the same reasons set forth above in response to the Examiner's anticipation and obviousness rejections over Sato alone.

Reconsideration and withdrawal of the Examiner's obviousness rejection of claims 15-17 over Sato in view of Hale are respectfully requested.

Obviousness Over Sato in View of Datar

In item 12 of the Office Action, the Examiner rejects claims 18, 32, and 33 pursuant to 35 U.S.C. § 103(a) over the Sato Patent in view of the Datar Patent. In the Examiner's view, the Sato Patent discloses devices that embody the recitations of the rejected claims, but for recitation in claim 18 of antibodies attached to the separation element and recitation in claims 32 and 33 relating to structure of the steps, and Datar discloses these antibodies and structures.

The Applicant respectfully demurs.

Even if Datar discloses attachment of antibodies as recited in claim 18 and relevant structural characteristics as recited in claims 32 and 33, Sato fails to obviate the remainder of the

apparatus claimed by the Applicant, for substantially the same reasons set forth above in response to the Examiner's anticipation and obviousness rejections over Sato alone.

Reconsideration and withdrawal of the Examiner's obviousness rejection of claims 18, 32, and 33 over Sato in view of Datar are respectfully requested.

Proposed Rejoinder

The Applicant respectfully believes that each of claims 2-19 and 31-35, as amended is in condition for allowance. Each of these claims is drawn to an apparatus.

The Examiner previously required restriction between claims directed to apparatus and claims directed to methods of using that apparatus.

Claims 20-25, 28-30, and 36 are presently withdrawn, but are method claims which recite use of the same apparatus recited in independent claims 31 and 34. These method claims require every limitation of at least independent claim 31. The Applicant respectfully contends that, if claims 31 and 34 are considered by the Examiner to be in condition for allowance, then claims 20-25, 28-30, and 36 should be rejoined, considered on their merits, and allowed as well. Such rejoinder is respectfully requested.

Summary

The Applicant respectfully contends that each of the Examiner's rejections in the Office Action should be reconsidered and withdrawn in view of the arguments presented herein and the amendments made to the Applicant's claims.

Consideration and allowance of each of claims 2-25 and 28-36 are respectfully requested at the earliest possible time.

Respectfully submitted,

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